

Al C. Edwards, M.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

IN RE DEPAKOTE: RHEALYN)	
ALEXANDER, et al.,)	
)	Case No.
Plaintiffs,)	12-52-NJR-SCW
)	
v.)	LEAD CONSOLIDATED
)	CASE
ABBOTT LABORATORIES INC.,)	
)	
Defendants.)	
_____)	

DEPOSITION OF AL C. EDWARDS, M.D.
Monday, October 3, 2016
Greenville, South Carolina
8:59 a.m.

REPORTED BY: Karen K. Kidwell, RMR, CRR

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1 BY MS. WILLIAMSON:

2 Q. Okay. Doctor, is a patient's decision
3 whether to take a medication a collaborative decision
4 made between the patient and the doctor?

5 A. The process is in my -- I've always felt
6 that the process is collaborative. The ultimate
7 decision is the patient's.

8 Q. Are you familiar with informed consent as
9 it relates to the practice of medicine?

10 A. Yes.

11 Q. And is this a very important concept in
12 medicine?

13 A. It is, yes.

14 Q. Does informed consent mean apprising the
15 patient of all important risk information that is
16 known to you about a drug?

17 A. It can, yeah. In all cases, not
18 necessarily all, but --

19 Q. In what cases would it not include that?

20 A. I'd have to -- I'd have to think a little
21 bit, but there are certainly people that we -- I
22 don't know if it's even applicable to this case that
23 you're talking about here, but there are folks that
24 have limited ability to understand all the nuances of
25 all the risks involved. And even though they may be

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1 MR. EVANS: Objection. Incomplete
2 hypothetical.

3 THE WITNESS: Sure.

4 BY MS. WILLIAMSON:

5 Q. In prescribing Depakote to Ms. Burnett in
6 1999, if Abbott had provided additional information
7 to you about the risks of birth defects with
8 Depakote, would you have shared that with your
9 patient, Ms. Burnett?

10 MR. EVANS: Objection. Incomplete
11 hypothetical.

12 THE WITNESS: I would hope I would have,
13 yes.

14 BY MS. WILLIAMSON:

15 Q. Because an important part of informed
16 consent is that the patient knows the relevant
17 benefit and risk of potential therapies, true?

18 A. Right, that's correct.

19 Q. Would you -- I think you testified to
20 this, but would you agree that it's the right of
21 every patient to control their own healthcare
22 decision?

23 MR. EVANS: Objection. Misstates prior
24 testimony.

25 THE WITNESS: Yes. I mean, in general,

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1 A. Yes.

2 Q. And after your discussion with the
3 patient, is it the patient's final decision what they
4 want to do generally?

5 A. Yes.

6 Q. And if a patient decides they don't want
7 to take a medication, would you expect and heed that
8 decision?

9 A. Sure. Probably wouldn't take it anyway.

10 Q. So the court and jury are clear about this
11 setting, based upon a full understanding of the
12 proposed risks, if either you or Ms. Burnett elected
13 to not accept the risk of Depakote and to opt for
14 another therapy, would Ms. Burnett have ever taken
15 Depakote in 1999?

16 MR. EVANS: Objection. Calls for
17 speculation.

18 THE WITNESS: Now, that was a lot of ifs.

19 BY MS. WILLIAMSON:

20 Q. So based upon a full understanding of the
21 proposed risk of Depakote, if you or Ms. Burnett had
22 decided not to accept that risk, would you have
23 prescribed Depakote to Ms. Burnett in 1999?

24 MR. EVANS: Objection. Calls for
25 speculation. Incomplete hypothetical.

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1 THE WITNESS: No.

2 BY MS. WILLIAMSON:

3 Q. And, Doctor, we've established that you
4 recommended that Ms. Burnett take Depakote in 1999
5 for possible seizure disorder, correct?

6 A. And it was being utilized as a mood
7 stabilizer as well and she had a history of
8 schizoaffective illness so it also may provide some
9 adjunctive treatment in that area.

10 Q. Was your decision to prescribe Depakote in
11 to Ms. Burnett in 1999 based upon your belief that
12 the benefits of the drug outweighed the risks based
13 on the information provided to you at the time?

14 A. Yes.

15 Q. And, Doctor, you were treating Ms. Burnett
16 with Depakote, not a baby, correct?

17 A. Correct.

18 Q. Okay. Do you have any independent
19 recollection of any conversations you had with
20 Ms. Burnett concerning any antiepileptic drug?

21 A. Other than what's in the record, I don't
22 have any -- really recollection of conversations like
23 that.

24 Q. 17 years ago?

25 A. Yeah.

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1 unpublished reports, valproic acid may produce
2 teratogenic effects in the offspring of human females
3 receiving the drug during pregnancy. There are
4 multiple reports in the clinical literature which
5 indicate that the use of antiepileptic drugs during
6 pregnancy results in an increased incidence of birth
7 defects in the offspring. Although data are more
8 extensive with respect to Trimethadione,
9 Paramethadione, Phenytoin and Phenobarbital, reports
10 indicate a possible similar association with the use
11 of other antiepileptic drugs."

12 Q. Thank you, Doctor. What does that convey
13 to you about Depakote as compared to other AEDs in
14 terms of overall risk to babies?

15 A. That it's basically on par with other
16 drugs.

17 Q. And is that consistent with what you knew
18 of the warning to be for the class of AEDs at that
19 time?

20 A. Pretty much, yes.

21 Q. Okay. All right. If you would read for
22 us, please, that next paragraph, "The incidence of
23 neural tube defects"?

24 A. "The incidence of neural tube defects in
25 the fetus may be increased in mothers receiving

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1 valproic acid during their first trimester of
2 pregnancy. The Centers for Disease Control, CDC, has
3 said the risk of valproic acid exposed women having
4 children with spina bifida to be approximately 1 to
5 2 percent."

6 Q. Doctor, if Abbott had information that the
7 incidence could be higher in 1999, would you have
8 wanted to know that at the time you prescribed
9 Depakote to Ms. Burnett?

10 MR. EVANS: Objection. Calls for
11 speculation.

12 THE WITNESS: Yes.

13 MR. EVANS: Sorry. Calls for -- assumes
14 facts not in evidence.

15 BY MS. WILLIAMSON:

16 Q. And your answer was?

17 A. Yes, I would want to know that.

18 Q. Okay. And then just that next paragraph
19 is the last one I'm going to ask you to read, please.
20 "Other congenital"?

21 A. "Other congenital anomalies, e.g.
22 craniofacial defects, cardiovascular malformations
23 and anomalies involving various body systems
24 compatible and incompatible with life have been
25 reported. Sufficient data to determine the incidence